STANDARD FOR PRODUCING HYGIENICALLY CLEAN REUSABLE TEXTILES FOR USE IN THE HEALTHCARE INDUSTRY

11/29/16

1. Scope

1.1. The purpose of this standard is to develop quality criteria for the production and certification of hygienically clean reusable textiles for use in healthcare facilities. Compliance with this standard is based on microbial (bacteriological) testing, documentation of laundry best management practices, and facility inspections.

1.2. This standard describes procedures for quality assurance; quality control inspections, sampling, and testing; minimum performance specifications; certification; outsourcing of services; non-compliance procedures; recordkeeping; and an appeal process to ensure the production of hygienically clean textiles.

1.3. This standard applies to reusable textiles used in healthcare facilities.

1.4. Bacteriological testing applies to hygienically clean textiles as they leave the laundry. Best practices documentation applies to all aspects of laundry processing including transportation of the textiles to their destination under the care and custody of the customer.

1.5. This standard does not address all safety or health issues associated with commercial or industrial laundry operations. It is the responsibility of the laundry facility to comply with all federal and state regulations (incorporating CDC and applicable guidelines) and operating permits.

2. Background

2.1. Please see Appendix 2 for a history of laundry certification programs.

3. Terminology

3.1. Definitions

3.1.1. Hygienically Clean: Free of pathogens in sufficient numbers to cause human illness.[1] This may be the most quoted definition for hygienically clean, yet no one has scientifically or quantitatively defined what the term "sufficient numbers" means. **For the purpose of this certification program textiles are considered hygienically clean if they comply with the Minimum Microbiological Performance Specifications in Section 8.2.**

3.1.2. A "Must" statement is one for which compliance is required.

3.1.3. "Shall", "Should", and "May" statements represent a best practice, are recommended for implementation, but are not mandatory.

[1] Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST 65:2008, *Processing of reusable surgical textiles for use in health care facilities*, 2008, Arlington, VA

4. Procedures

4.1. Application – Application must be made for TRSA certification of hygienically clean reusable textiles on forms supplied by TRSA.

4.2. Fees – Each application must be accompanied by an application fee as set forth in the TRSA Hygienically Clean Fee Schedule. Your application fee will expire if your facility is not certified within 12 months.

4.3. Processing - Upon receipt of the application and application fee, the paperwork will be processed to completion under the guidelines for certification in Sections 5, 6, 7, and 8.

4.4. Testing – Testing may begin prior to the submission of the application. Initial test results must be submitted 60 days after the submission of your application. Secondary test results must be submitted no later than 45 days after the initial results are received.

4.5. Compilation of Quality Assurance Manual - The quality assurance manual should be compiled during the testing phase. An inspection must be scheduled within 60 days of the secondary sample submission meeting the standard requirements.

4.6. Certificate of Compliance – For each application that certification is granted, a Certificate of Compliance stating conformance to production of hygienically clean textiles will be issued. The facility will then be given permission to use the TRSA logo indicating conformance to this standard.

4.7. Right to Appeal – The client has the right to appeal any decision by TRSA in executing any provisions in this standard. See Appendix 1 on Appeals.

4.8. Revocation, Suspension, or Modification of Certification – Certification may be revoked, suspended, or modified for any of the following reasons.

- Failure to comply with the provisions of this standard.
- Any misstatements, intentional or unintentional, made in the application or in any data submitted in support of the application.
- Failure to comply with the certification criteria contained in this standard.
- Any other grounds considered reasonable in the judgment of TRSA which leads to the conclusion that the textiles produced by the laundry do not meet the criteria established under this standard.

5. Quality Assurance Program

Each facility shall have a written Quality Assurance (QA) manual to reasonably ensure that Best Management Practices are documented and followed for the production of hygienically clean textiles and the facility complies with all federal and state regulatory requirements. The Quality Assurance manual should encompass applicable infection control guidelines established by the Centers for Disease Control and Prevention (CDC) as well as recommended practices from The Joint Commission (TJC – formerly JCAHO) relevant to the handling and processing of healthcare textiles.

5.1. Best Management Practices (BMPs)

The Quality Assurance manual shall incorporate the following Best Management Practices that are important to the production of hygienically clean textiles. How the facility complies with each BMP must be documented and the documentation will be a key focus when a TRSA inspector visits a laundry to conduct an inspection. Laundry BMPs subject to mandatory federal regulations covered in Section 5.2 - Compliance with OSHA Regulations will not be duplicated in this Best Management Practices section. Examples of BMPs covered in Section 5.2 and not in Section 5.1 include, but are not limited to, Engineering and Work Practice Controls (Section 5.2.1.5) and Personal Protective Equipment (Section 5.2.1.6).

5.1.1. Plant Facilities

5.1.1.1. Functional separation of soiled and clean areas

The QA manual shall describe how the soiled and clean areas of the laundry are functionally separated. Functional separation can be obtained in several ways, including establishing a physical barrier between clean and soiled areas of the laundry, a negative air pressure system in the soiled linen area, or a positive air flow from clean through soiled areas[2]. Whatever system is implemented, the laundry must be able to document and demonstrate to the inspector the functional separation is effective. Soiled textiles must never be transported or stored in the clean areas of the plant, and clean textiles shall never be transported or stored in the soiled areas of the plant. Flow of textiles shall always be from soiled to clean.

5.1.1.2. Equipment and equipment maintenance

The QA manual shall contain a list of all major equipment, including washers, dryers, finishing equipment, etc. A written maintenance schedule for each piece of equipment as prescribed by the manufacturer or appropriate regulatory requirement shall be included in the QA manual. Maintenance records shall be recorded and maintained for at least six-years and be made available for review by the TRSA inspector.

5.1.1.3. Equipment Calibration

The QA manual shall describe the procedures for calibration of equipment and controls. This includes temperature gauges, flow controllers, and any other measurement devices critical to keeping the equipment and chemical dispensing apparatus operating to manufacturer's specifications. Calibration records must be documented, made available to the TRSA inspector, and maintained for six years.

[2] Textile Rental Services Association of America, *Guidelines for Healthcare Linen Service-1999*, By Joint Committee on Healthcare Laundry Guidelines, Alexandria, VA, 1999

5.1.1.4. Pest Control Program

Each laundry-processing plant should have documentation of a current integrated pest management (IPM) program consistent with healthcare-recommended practices and with evidence of scheduled treatments. (CDC-HICPAC GL, 2003: II.E.V.A-C; ASHES Recommended Practice Series: Integrated Pest Management)

5.1.2. Housekeeping

The QA manual shall describe in detail procedures for the following housekeeping functions.

5.1.2.1. Use, cleaning and care of equipment

5.1.2.2. Cleaning of work surfaces and stations

5.1.2.2.1 Slings that might be used in the production processes – soil or clean

5.1.2.3. Cleaning of carts

5.1.2.3.1 Transportation carts that are used to transport soil and then used to transport clean back to the customer

5.1.2.3.2 Carts that are used internally within the plant to transport work in process to different production stations

5.1.2.3.3 Any other linen cart or linen container that is used to transport, store, or deliver clean linen/textiles (e.g., exchange carts)

5.1.2.4. Selection, measurement and proper use of cleaning supplies

5.1.2.5. Cleaning schedule

5.1.3. Laundry Process

5.1.3.1. Soiled linen handling

Procedures for handling soiled linen shall be documented in the QA manual. Soiled linen should be handled as little as possible, and the manual shall describe when use of personal protective equipment is mandatory based on compliance with the OSHA Bloodborne Pathogen standard.

5.1.3.2. Washing Procedures

- Wash Formulas

Each classification shall have established standard wash formulas for the following factors to optimize the cleaning and the productivity of the wash process:

- Cycle time: Pre-wash, wash, rinse, and final rinse times
- Water levels/usage: Total water usage and/or water levels;
- Temperature: Wash cycle, bleach cycle, and rinse cycle temperatures;
- Chemical usage: Chemical types and usage levels for each step in the wash process.

- Wash Temperature
  Hot-water washing – if hot water is used the water temperature shall be at a temperature prescribed by the chemical manufacturer.
  Low-temperature water washing – if low-temperature (<70°C) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentrations, as prescribed by the chemical manufacturer, shall be used[9].
- Use of disinfectants, e.g. chlorine
  The circumstances, conditions, and procedures regarding when bleach or other disinfectants are added shall be described in the quality assurance manual.
- Final pH

Each classification shall be soured to a pH which is suitable for skin compatibility and for proper finishing processes.

- Extraction

The provider shall extract and/or dry the clean healthcare textiles in a manner that preserves the integrity of the textiles, minimizes microbial growth after washing, and prepares the textiles for efficient ironing or folding. Damp textiles shall not be inappropriately stored (e.g., tightly packed and poorly ventilated) as this may prevent drying and facilitate microbial growth.

5.1.3.3. Drying Procedures

- The drying procedures shall be controlled and monitored for each textile classification to ensure appropriate drying.
- Hot, dry loads should be subjected to sufficient cool-down to enable personnel to handle the textiles comfortably and to minimize wrinkling.
- Drying must be done in a manner which ensures textiles are dried to proper moisture content without subsequent bacterial recontamination. Cleaned, dried goods must be separated from all soiled goods.

5.1.3.4. Transportation

The QA manual shall describe in detail procedures for the following functions.

- The process for servicing accounts must be designed and executed to prevent cross-contamination
- Trained service reps arrive for scheduled pick-up/delivery.
- Items should be transported in designated approved covered containers.
- Service trucks should be cleaned on a regular basis to minimize infection and contamination.
- Trucks should be swept out daily and decontaminated at least twice a month.
- Reusable cart covers must be cleaned after every use.
- Proper PPE and gloves must be worn at all times when handling soiled linen.

- All linen retrieved from a customer location and delivered to the soiled processing area must be cleaned prior to delivery to the customer.
- All clean and unused linen retrieved from a customer location that is transported in designated, approved, and covered containers that maintain proper functional separation, and is delivered to the clean processing area may be rotated and restocked prior to delivery to the customer.
- A designated transition area with controls must be identified to remove potentially soiled cart covers prior to delivering exchange carts to the clean processing area.

5.1.3.5. Delivery

The QA manual shall describe in detail procedures for the following functions.

- The functional separation concept must continue during transportation of clean textiles to the healthcare customer.
- Transport clean and soiled linen in containers that functionally separate them from other linens in the vehicle.
- Consider cleaning and packaging.
- Reusable bags, containers, and carts used to transport soiled linen must be properly cleaned before they are used to transport clean or soiled linen in order to maintain functional separation.
- The term "properly cleaned" means either steam-cleaned or cleaned with an EPA approved cleansing agent/ disinfectant and water solution. (accurately mixed as directed by the manufacturers' instructions).
- Hand sanitizer must be available for use in all delivery trucks. Employees must be trained on proper hand hygiene, and proper hand hygiene BMP's must be followed. Spill Kits should also be available for use when necessary.
- Laundries should package, transport, and store clean textiles and fabrics by methods that will ensure their cleanliness and protect them from dust and soil during interfacility loading, transport, and unloading. (CDC/HICPAC)

5.1.3.5.1. Use of Exchange Carts

- Service representatives must follow BMPs associated with rotating and restocking customer linen levels to overcome the risk of accidental long-term storage of linen at customer sites.

5.2. **Compliance With OSHA Regulations**

The QA manual shall contain, at a minimum, a copy of the following regulations.

- 29 CFR 1910.1030…… Bloodborne pathogens
- 29 CFR 1910.1030 App A…… Hepatitis B Vaccine Declination (Mandatory)
- 29 CFR 1910.1200…… Hazard Communication
- 29 CFR 1910.1200 App E……. Guidelines for Employer Compliance (Advisory)

The Quality Assurance manual shall describe how the facility implements each of the following OSHA requirements.

5.2.1. **OSHA 29 CFR 1910.1030 Bloodborne Pathogens Required Practices**

5.2.1.1. Exposure Control

- Universal Precautions

5.2.1.2. Exposure Control Plan

5.2.1.3. Exposure Determination

5.2.1.4. Methods of Compliance

5.2.1.5. Engineering and Work Practice Controls

- Handwashing facilities readily available to employees
- No eating, drinking, smoking, applying cosmetics, or handling contact lenses in work areas where there is a reasonable likelihood of occupational exposure

5.2.1.6. Personal Protective Equipment

- Provision
- Use
- Accessibility
- Cleaning, Laundering, and Disposal
- Repair and Replacement
- Masks, Eye Protection, and Face Shields
- Gowns, Aprons, and Other Protective Body Clothing

5.2.1.7. Housekeeping

- Cleaning of work surfaces
- Protective covering replacement
- Cleaning of receptacles intended for reuse
- Handling of potentially contaminated broken glassware
- Regulated Waste

5.2.1.7..1. Contaminated Sharps Discarding and Containment

5.2.1.7..2. Other Regulated Waste Containment

- Laundry

5.2.1.7..1. Handling of contaminated laundry

5.2.1.8. Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up

5.2.1.9. Communication of Hazards to Employees

- Labels and signs
- Information and Training

5.2.1.10. Recordkeeping

- Medical Records

  5.2.1.10..1. Must comply with 29 CFR 1910.1020
- Training Records
- Availability
- Transfer of Records
- Sharps Injury Log

5.2.2. **OSHA 1910.1200 Hazard Communication Required Practices**

5.2.2.1. 1910.1200(a) Purpose

5.2.2.2. 1910.1200(b) Scope and application

5.2.2.3. 1910.1200(c) Definitions

5.2.2.4. 1910.1200(d) Hazard Determination

5.2.2.5. 1910.1200(e) Written hazard communication program

5.2.2.6. 1910.1200(f) Labels and other forms of warning

5.2.2.7. 1910.1200(g) Material safety data sheets

5.2.2.8. 1910.1200(h) Employee Information and training

5.2.2.9. 1910.1200(i) Trade secrets

5.2.3. **Compliance with OSHA 1910.1200 Hazard Communication App E – Guidelines for Employer Compliance (Advisory)**

5.2.3.1. "Becoming familiar with the rule"

5.2.3.2. "Identify Responsible staff"

5.2.3.3. "Identify Hazardous Chemicals in the Workplace"

5.2.3.4. "Preparing and Implementing a Hazard Communication Program"

- "Labels and Other Forms of Warning"
- "Material Safety Data Sheets"
- "Employee Information and Training"
- "Other Requirements"

5.2.3.5. "Checklist for Compliance"

- Obtained a copy of the rule.
- Read and understand the requirements
- Assigned responsibility for tasks.
- Prepared an inventory of chemicals.
- Ensured containers are labeled.

- Obtained MSDS for each chemical.
- Prepared written program.
- Made MSDSs available to workers.
- Conducted training of workers.
- Established procedures to maintain current program.
- Established procedures to evaluate effectiveness.

6. Facility Inspections

6.1. General

Inspectors shall have access to certified facilities during normal business hours to conduct inspections for the purpose of determining compliance with this standard. Inspections will be scheduled at a mutually agreeable time between the TRSA inspector and the laundry facility. Expenses incurred by TRSA for on-site inspections shall be the responsibility of the facility seeking certification.

6.2. Initial Qualification Inspection

6.2.1. An initial on-site inspection must be conducted by a representative of TRSA to evaluate compliance with the provisions of this standard.

6.3. Quality Control Inspections

6.3.1. After the initial on-site inspection, facilities shall be inspected on a three-year basis.

6.3.2. An additional supplemental inspection may be conducted within the three-year period.

7. Sample Selection for Bacteriological Testing

7.1. General

7.1.1. In all cases items are to be shipped to the laboratory in separate air-tight plastic bags or plastic wrapping that are labeled with the following information.

- Name of laundry
- Location of laundry (number and street, city, state, zip code)
- Name of contact person for this facility
- Contact phone number and e-mail
- Date of production
- Textile description
- Items should be mailed using an overnight or two day delivery service.
- Remember to include the chain of custody form in the box

7.2. Initial Qualification

For initial qualification of a facility the Contacts in the plant shall select 2 textiles for bacteriological testing. (**one terry item and one flat items**) Samples must pass testing on three consecutive rounds and the plant must pass inspection prior to qualification. Samples shall be shipped to a laboratory chosen by the facility that is on the TRSA-approved laboratory list. Samples should include, but are not limited to: Bath Blankets, Towels, Washcloths, Pillow Cases, Sheets, Mattress Pads, Underpads, Bed Spreads, Blankets, Scrub tops, Scrub bottoms, Lab Coats, Patient Gowns, Baby Tees.

7.3. Probationary Period

7.3.1. The probationary period ends when three consecutive months of bacteriological testing meet the minimum Microbiological Performance Specifications outlined in Section 8.2 and the plant has passed inspection. Bacteriological testing of textile items will be conducted in each of the first three months. After the initial samples meet the microbiological criteria, (Section 7.2.1 above), textile samples shall be selected on a rotating basis such that in the first three months six different textile items are tested. **Plants will be allowed to resubmit/re-test one failed test result in the probationary period. If a failed test result is received, the plant must immediately resubmit the same item for testing to the same test lab. See 7.8.1**

7.4. Quality Control Microbial Testing

7.4.1. After successful completion of the precertification period, microbial testing will be conducted on a quarterly basis.

7.4.2. Four times yearly, two textile items will be submitted by plant personnel to an approved laboratory for bacteriological testing. Samples shall be selected on a rotating basis, with a goal of testing twenty eight (28) different textile items at least once in the first three-year period.

7.4.3. Should any textile item fail quarterly bacteriological testing, TRSA may require that product to be one of the textiles tested quarterly until it is reasonably assured there are no compliance issues.

7.5. Triennial On-site Inspections

7.5.1. At least once every three years a TRSA representative shall physically visit each laundry facility and select two items for microbial testing. The products selected shall be those projected to have the highest potential to fail to meet the minimum performance specifications in Section 8.2 based on previous microbial testing. The representative will ship the samples to a TRSA-approved laboratory chosen by the client for microbial testing.

7.6. Significant Process Change Testing

7.6.1. When a facility makes a significant change in the laundry process that may affect compliance with this standard, e.g. major washing equipment or chemistry changes, a bacteriological test on the two most prominent healthcare textile items processed shall be conducted to confirm the facility remains in compliance.

7.7. Optional Testing

7.7.1. A laundry may conduct additional bacteriological testing at their discretion. Test results must be immediately reported to TRSA after receipt.

7.8. Non-compliance Testing

7.8.1. Upon notification of a test failure, the facility shall contact TRSA, immediately select a sample of the textile item that failed for re-test, and ship it by next-day-air to the same laboratory that conducted the non-complying test. Test results must be provided to TRSA as soon as the test results are available.

8. Quality Control Microbial Testing

8.1. All testing shall be done by a TRSA-approved laboratory that is accredited by any accreditation body recognized under the ILAC MRA (Mutual Recognition Arrangement) or recognized by federal or state agencies for microbiological testing. Examples of acceptable third-party accreditation bodies include the International Accreditation Service (IAS), American Association of Laboratory Accreditation (A2LA), and ANSI-ASQ National Accreditation Board doing business as ACLASS. Laboratories recognized by federal or state agencies such as EPA, FDA, Department of Agriculture, CDC, CPSC, and OSHA are also approved.

8.2. Minimum Microbiological Performance Specifications

Microbial and Yeast/Mold testing shall be performed using the following test methods: RODAC Plate count quarterly and United States Pharmacopeia (USP) 62 semi-annually.

United States Pharmacopeia (USP) 62 - Microbiological Enumeration of Nonsterile Products: Microbial Examination Tests. See current pass/fail criteria below. Methods and criteria are continuously reviewed and subject to revision.

RODAC Plate Test	Pass/Fail Criteria
Total aerobic microbial count (TAMC)	Acceptance criterion for microbiological quality: ≤ 20 cfu per square decimeter
Total Yeast and Mold count (TYMC)	Acceptance criterion for microbiological quality: ≤ 20 cfu per square decimeter

Test Method USP 62		Pass/Fail Criteria
Specified Microorganisms		Acceptance criterion for microbiological quality: Absent

8.2.1. Laboratories shall provide copies of all test reports to the laundry facility and TRSA.

9. Certification

9.1. Facility Certification

Evaluation of the facility's application, facility inspection, and test data will result in:

- TRSA certification of the laundry as complying with the requirements in this standard for producing hygienically clean textiles, or
- Disapproval for lack of evidence justifying certification to the requirements of this standard (See section 4.5 – Right to Appeal and Appendix 1 – Appeals, Complaints, and Resolution of Disputes.)

10. Outsourcing

10.1. If a facility is unable to fulfill its obligations or agreements for any reason and must outsource work to another laundry, extension of the TRSA Hygienically Clean certification to the outsourced textiles will be restricted as follows.

10.1.1. If the outsource laundry is also certified by TRSA, the TRSA certification logo may be used to indicate the textiles are certified as hygienically clean.

10.1.2. If the outsource laundry is not certified by TRSA, no documentation, e.g. invoices, bills-of-lading, or any other form of correspondence associated with the laundry processed by the outsource laundry may carry the TRSA certification logo. If the customer expects TRSA Hygienically Clean certified textiles through contracts or other agreements, the customer must be made aware the textiles processed by the outsource laundry are not certified to the TRSA Hygienically Clean – Healthcare standard.

11. Non-compliance Procedures

After certification is awarded to a facility, any non-compliance issues found in a subsequent inspection report or non-complying test result shall be reported to TRSA by phone or e-mail within 24-hours or the next business day if notification falls on a weekend or holiday. Non-complying test results shall be defined as failure to meet the Minimum Microbiological Performance Specifications in Section 8.2.

11.1. Corrective Actions

11.1.1. For each incidence of non-compliance a Corrective Action Request (CAR) shall be issued. The facility has 30-days to respond to the CAR and bring the plant back into compliance. If corrective action is taken within 30-days to bring the facility back into compliance the certification will not lapse. Failure to completely address all CARs within 30-days will result

in certification being revoked, suspended, or modified depending on the severity of the non-compliance issue.

11.2. Reinstatement Following Revocation or Suspension of Certification

11.2.1. After a facility is brought back into compliance certification is reinstated and a new probationary period started. Bacteriological testing following the procedures in Section 7.4 must be conducted until test results from three consecutive months are in compliance with Section 8.2.

12. Recordkeeping

All applications, inspection records, and test results shall be maintained by TRSA and the laundry for as long as a facility is certified plus an additional three years.

13. References

[1] Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST 65:2008, *Processing of reusable surgical textiles for use in health care facilities*, 2008, Arlington, VA

[2] Textile Rental Services Association of America, *Guidelines for Healthcare Linen Service-1999*, By Joint Committee on Healthcare Laundry Guidelines, Alexandria, VA, 1999

[3] The Healthcare Laundry Accreditation Council (HLAC), *Healthcare Accreditation Standards for Processing Reusable Textiles for Use in Healthcare Facilities 2011 Edition*, Frankfort, IL, June 2011

[4] Association for the Advancement of Medical Instrumentation, *ANSI/AAMI ST65:2000, Processing of Reusable Surgical Textiles for Use in Health Care Facilities*,

[5] Standards Australia and Standards New Zealand, AS/NZS 4146:2000, *Australian/New Zealand Standard – Laundry practice,* February 2000

[6] German Institute for Standardization, European Standard EN 14065 : 2002*, Laundry processed textiles – Biocontamination control system*, Berlin, Germany, November 2002

[7] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), *Guidelines for Environmental Infection Control in Health-Care Facilities*, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), Atlanta, GA, 2003

[8] German Certification Association for Professional Textile Services, RAL-GZ 992/2 – Hospital Linen, Bönnigheim, Germany

[9] Institute for Sustainability and Hygiene International, *Certification Standards for Processing Reusable Linen*, MacKenzie, Brisbane, Queensland, Australia, April 2011

Appendix 1

Appeals, Complaints, and Resolution of Disputes

1.0 PURPOSE/SCOPE

The purpose of this procedure is to describe the process for identifying, recording, and resolving applicant or certificant complaints, inspection and testing non-conformances, and appeals of certification decisions. This procedure applies to all TRSA employees and inspectors engaged in certification, inspection and testing activities and to all applicants and certification holders, hereinafter referred to collectively as "Customers."

2.0 RESPONSIBILITY

TRSA personnel are responsible for:

- Recognizing and accurately recording each Customer complaint;
- Notifying and forwarding Customer complaints to the TRSA Manager of Certification Programs; and
- Maintaining confidentiality and avoiding conflicts of interest.

The Manager of Certification Programs is responsible for:

- Making an initial evaluation of each Customer complaint or appeal;
- Investigating the cause of the complaint or appeal;
- Developing a corrective action plan; and
- Ensuring the Customer understands the rationale for the resolution of the complaint or appeal.

3.0 PROCEDURES

3.1 Administrative Review of Complaint or Appeal

When a complaint or appeal is received by TRSA, it shall be documented on a TRSA Disposition Form. The Manager of Certification Programs shall examine all pertinent data and any decisions based upon the data. The disposition form, results of the review and recommended actions shall be put into a report by the Manager of Certification Programs. If further action is deemed necessary, TRSA will retest or re-inspect and reissue the appropriate report. If the new data impacts a certification decision, a new decision shall be documented and issued. Should this Administrative Review fail to resolve the complaint or appeal, the matter shall be referred to the Technical Review Board.

3.2 Resolution of Compliant or Appeal by the Technical Review Board

If a dispute arises between a Customer and TRSA that cannot be resolved by the initial Administrative Review and recommended actions, the Customer may obtain a review of the complaint or appeal by the Technical Review Board. The Customer shall present to the Manager of Certification Programs of TRSA a written statement of its position. The matter shall then be referred to the Technical Review Board. The Customer shall be offered a full opportunity, in person and by counsel if desired, to be heard by and to present any relevant additional evidence to the Technical Review Board. Unless otherwise agreed to in writing by both parties, the Technical Review Board will make a final decision on the matter within fourteen (14) days.

3.3 Technical Review Board (TRB)

The Technical Review Board shall consist of three members and two alternates. The members and the alternates shall be appointed by the TRSA Board of Directors from TRSA member companies. Any Technical Review Board member or alternate who has a conflict of interest or is otherwise unable to maintain impartiality shall be ineligible to participate in the appeal. In such event, the Board of Directors shall appoint one of the alternates to serve on the Technical Review Board for that appeal. Decisions of the Technical Review Board shall be final.

4.0 RECORDS

The Manager, Certification Programs shall maintain a log and records of all customer complaints and appeals and the details and results of investigations and corrective actions. Records shall be maintained for the duration of the contract plus five years.

Appendix 2

Laundry Certification Background

Historically certification of laundries processing reusable textiles for use in the healthcare industry has been based on the laundry process with no requirement for microbial (bacteriological) testing of products. Certification standards in the United States[3,4], Australia and New Zealand[5], and Europe[6] all base certification on a laundry's process with no mandatory microbial testing of textile products.

In the United States the status quo is no bacteriological testing of reusable textiles. This may be the result of statements made by the U.S. Centers for Disease Control (CDC) in their *Guidelines for Environmental Infection Control in Health-Care Facilities*[7]. Three quotes from the CDC Guidelines shed light on the reasons the CDC does not recommend routine microbiologic testing.

1. "Before 1970, U.S. hospitals conducted regularly scheduled culturing of the air and environmental surfaces (e.g. floors, walls, and table tops). By 1970, CDC and the American Hospital Association (AHA) were advocating the discontinuation of routine environmental culturing because rates of health-care-associated infection had not been associated with levels of general microbial contamination of air or environmental surfaces, and because meaningful standards for permissible levels of microbial contamination of environmental surfaces or air did not exist." (pg. 88)

2. "**In the absence of microbiologic standards for laundered textiles, no rationale exists for routine microbiologic sampling of cleaned health-care textiles and fabrics**. (emphasis added)" (pg. 102)
3. "Although contaminated textiles and fabrics in health-care facilities can be a source of substantial numbers of pathogenic microorganisms, reports of health-care-associated diseases

[3] The Healthcare Laundry Accreditation Council (HLAC), *Healthcare Accreditation Standards for Processing Reusable Textiles for Use in Healthcare Facilities 2011 Edition*, Frankfort, IL, June 2011
[4] Association for the Advancement of Medical Instrumentation, *ANSI/AAMI ST65:2000, Processing of Reusable Surgical Textiles for Use in Health Care Facilities*,
[5] Standards Australia and Standards New Zealand, AS/NZS 4146:2000, *Australian/New Zealand Standard – Laundry practice,* February 2000
[6] German Institute for Standardization, European Standard EN 14065 : 2002*, Laundry processed textiles – Biocontamination control system*, Berlin, Germany, November 2002
[7] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), *Guidelines for Environmental Infection Control in Health-Care Facilities*, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), Atlanta, GA, 2003

linked to contaminated fabrics are so few in number that the overall risk of disease transmission during the laundry process likely is negligible." (pg. 98)

The take-away from this CDC document is routine microbiologic testing is not necessary.

While the CDC does not recommend routine microbial testing of cleaned healthcare textiles and fabrics, testing for compliance in a certification program is not routine testing; it is testing to validate compliance with a performance-based standard. TRSA's certification program is predicated on microbial testing for several reasons. The trend, both domestically and internationally, is moving toward microbial testing of reusable textiles for use in healthcare facilities. Today, some hospitals and other healthcare facilities are asking members of TRSA to conduct microbial testing on their textiles. Internationally, the German Certification Association for Professional Textile Services RAL – Hygiene Certificate Program includes mandatory microbial testing of textiles[8]. In Australia, the Institute for Sustainability and Hygiene International's Certification Standards for Processing Reusable Linen[9] CSHLS program also requires mandatory microbial testing.

TRSA does not believe lack of mandatory testing under federal or state regulations in the U.S. is a compelling reason not to include mandatory microbial testing in our certification program. Requiring independent, third-party testing provides our customers with tangible evidence that the textiles they are using are hygienically clean, and verification that the commercial laundry process does what it is recognized by the CDC to do – result in production of hygienically clean reusable textiles.

The frequency of microbial testing selected for this certification program is not based on any federal or state regulatory requirements because none exist. No testing regimen selected would have a statistical basis as there is no database to draw from. This standard is the first of its kind in the U.S. requiring microbial testing. As stated earlier, the referenced domestic and international laundry standards[1, 2, 3, 4] certify laundries based on the laundry process with no mandatory microbial testing. With the existing paradigm for laundry certification, any testing frequency is an improvement over the status quo of no testing. For this certification program, testing will be conducted in each of the first three months of certification, followed by semiannual testing if all testing in the first three months passes the criteria established in Section 8.2.

Selection of the bacteria to target for certification testing was also a challenge for the same reasons stated in the previous paragraph. Lack of federal and state guidelines and the CDC statement of fact that there are no microbiologic standards for laundered textiles led to an Internet search for potential resources to identify which bacteria should be targeted. The CDC publishes a list of the top ten pathogens that account for 84

[8] German Certification Association for Professional Textile Services, RAL-GZ 992/2 – Hospital Linen, Bönnigheim, Germany

[9] Institute for Sustainability and Hygiene International, *Certification Standards for Processing Reusable Linen*, MacKenzie, Brisbane, Queensland, Australia, April 2011

percent of all Healthcare-associated Infections (HAIs). In addition to bacteria to identify for testing, it was decided a test method must be identified so all testing laboratories would use the exact same procedures to identify the bacteria present. And finally, a survey was conducted to determine the bacteria being tested for

when laundries are asked to conduct microbial testing by healthcare customers. The two bacteria that stood out were staphylococcus aureus and pseudomonas aeruginosa, both of which are on the CDC Top 10 list. Other research indicated Escherichia coli (E-coli) was a very important bacteria to target.

Based on this internet research two test methods stood out. Test method United States Pharmacopeia (USP) 62 – *Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms* targets all three of these bacteria that are on the CDC Top 10 list as well as a fourth, candida albicans. This test method is considered by TRSA to be a microbiological test for hygienically clean as defined in Section 3 of this standard and was selected for our certification program.

USP 61 - *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*, is a quantitative enumeration of mesophilic bacteria (a microorganism that grows best at 68° to 131°F (20° to 55°C)) and fungi that may grow under aerobic conditions. The pass/fail criterion selected for the TRSA hygienically clean certification program is ≤ 20 cfu, the lowest acceptance criterion for microbiological quality in USP 61.

RODAC-Replicate Organism Detection And Counting Microbiological test is modeled on European Standards.

Commercial laundries have been operating for over a century with virtually no link between reusable textiles and pathogenic disease transmission to healthcare patients or healthcare workers. There are no federal or state regulations requiring a laundry to be certified. There are no federal or state standards requiring microbial testing of reusable textiles. TRSA feels this standard, with mandatory microbial testing, is “raising the bar” in certifying laundries for producing hygienically clean reusable textiles.